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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,423	10/16/2001	Avi J. Ashkenazi	GNE.2630P1C21	5291

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,423	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *58-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/06/02 and 12/13/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

The Examiner acknowledges applicant's Preliminary amendment, mailing date of 10/16/01, requesting the addition of claims 58-63 and the cancellation of claims 1-57. In view of the amendment, the status of the claims is:

Claims 1-57 are canceled. Claims 58-63 are added. Claims 58-63 are currently under examination.

Priority

1. According to the priority statement of 09/03/02, it appears that the claimed subject matter defined in the instant application is supported by the parent application serial no. 60/080328. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. 60/080328, filed 04/01/98. Accordingly, the subject matter defined in claims 58-63 has an effective filing date of 04/01/1998.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 04/01/1998 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 04/01/1998.

2. Claim 63 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 63 recites an antibody of claim 58 that specifically binds to SEQ ID NO: 375. The claim does not further limit claim 58 because claim 58 recites an antibody that binds to SEQ ID: 375.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 58-63 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are direct toward an antibody that binds to a disclosed polypeptide, SEQ ID NO: 375.

Applicant's assertion that the claimed antibody can be used in diagnostic assays for the disclosed polypeptide, e.g., detection its expression in specific cells, tissues, or serums (line 32-35,page 224, specification), is not specific and substantial utility for the antibody. The antibody lacks a specific and substantial utility because no where in the specification has Applicant indicate a specific and substantial utility for the polypeptide that is detected by the antibody of the instant invention. Applicant's assertion that the polypeptide is expected to be useful in the treatment of neurological conditions which

are associated with undesirable neural cell proliferation including neuroblastomas, gliomas, gliobastomas, and the like, after the polypeptide tested positive in the rat DRG neuronal survival inhibition assay is not specific and substantial. The purpose of a DRG neuronal survival inhibition is to detect a polypeptide's ability to inhibit survival of neural cells only, not a polypeptide's ability to treat neurological conditions. The inference of utility for the polypeptide made by Applicant, in view of the results from the assays, is not adequate to yield a specific and substantial utility for the polypeptide. Thus, without a specific and substantial utility for the polypeptide, the antibody that binds to the polypeptide also lacks a specific and substantial utility.

Claims 58-63 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 58 and 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an antibody that specifically binds to a polypeptide, SEQ ID NO: 375.

The recitation of "specifically binds to" in the claims can imply that the antibody is exclusive of the polypeptide or that the antibody binds to a particular antigenic epitope of the polypeptide. However, no where in the specification does Applicant teaches specific bindings of the antibody to the disclosed polypeptide. The disclosure, line 27, page 106 of the specification, concerning antibody and specifically binding is inadequate to reasonably convey to one skilled in the relevant art that Applicant, at the time application was filed, had possession of an antibody that "specifically binds to" SEQ ID NO: 375. The specification does not provide any teachings concerning "specifically binds to" nor has Applicant provides an epitope mapping of the polypeptide that would enable one of ordinary skills in the art to conclude that the "specifically binds to" site is a particular antigenic epitope.

7. Claims 68 and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In Genentech *Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (Bd Pat App Int 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F. 2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

The quantity of experimentation necessary to find an antibody that is exclusive of the disclosed polypeptide or any antibody that binds to the polypeptide is generally high.

The amount of guidance provided from the specification concerning "specifically binds to" could not be found within the specification.

The specification provides no working examples of the functions and characteristics required of the antibody to binds to the disclosed polypeptide.

The nature of the invention is an antibody that specifically binds to a polypeptide, SEQ ID NO: 375.

The state of the art is such that it is known in the art that an antibody can binds to any polypeptide that have the same antigenic epitope.

The relative skill of those in the art is high.

The art concerning specific binding of antibodies to polypeptides is relatively unpredictable.

The claimed invention is described with specific language such as "specifically binds to". The breadth of the claims is very narrow, which is also not enabled by the specification.

Therefore, the instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands* lacks an enabling disclosure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 58-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Ichtchenko et al, ("Neuroligin 1: A Splice Site-Specific Ligand for β–Neurexins", 1995).

The claims are directed to an antibody that binds to a polypeptide, specifically SEQ ID NO: 375.

Ichtchenko et al. teach a neuroligin polypeptide, where residues 546-595 of the polypeptide is the same as that of residues 510-559 of SEQ ID NO: 375. Further, Ichtchenko et al. teach the use of antibody that is specific to the polypeptide to study the binding properties of neuroligins (last paragraph of page 2679). Thus, because of common epitope that exists in both polypeptides, it is expected that the antibody that binds to the polypeptide taught by Ichtchenko et al. would bind to the claimed polypeptide, SEQ ID NO: 375. Therefore, Ichtchenko et al. anticipated the instant invention.

The claims are further limited to monoclonal, humanized, antibody fragment, and a labeled antibody. Although, Ichtchenko et al. do not specifically teach a monoclonal, humanized, antibody fragment, and a labeled antibody, which Applicant is claiming in the instant invention, it would have been obvious for one of ordinary skills in the art to raise such antibody. The production of monoclonal, humanized, antibody fragment, and labeled antibodies is well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (703) 305-4452. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

E.Le

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER